UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,715	08/16/2006	Abelardo Silva	00956.8006.US02	3064

91106 7590 04/28/2010

Perkins Coie LLP
607 Fourteenth Street, NW
Washington, DC 20005

EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
04/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentprocurement@perkinscoie.com

Office Action Summary	Application No.	Applicant(s)	
	10/550,715	SILVA ET AL.	
	Examiner	Art Unit	
	ROY TELLER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-28 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *18-28,30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment, received 1/21/10, in which claim 24 has been amended.

Claims 48, 53, 81 and 136-145 are withdrawn as being drawn to non-elected subject matter. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 18-28 and 30 are under examination.

Response to Amendments/Arguments

Applicant's arguments and amendments filed 1/21/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18, 19, 23, 24, 25, and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 9, and 10 of copending Application No.10/ 478,811. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a complex of formula I: wherein Av is AV is WMEWDREINNYTSLIHSLIEESQNQQEKNEQELL, linkers, and Pr is human serum albumin (HSA), wherein the complex possesses antiviral activity. The '811 application discloses a compound of formula I-VIII that includes the WMEWDREINNYTS LIHSLIEESQNQQEKNEQELL peptide, linker, and albumin that inhibit viral activity (HIV, HPV or MeV).

This is an obviousness-type double patenting rejection because the conflicting claims have matured into a patent on 3/30/10. Therefore, applicant's request to hold the rejection is abeyance is rendered moot by the allowance of the '811 application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-28 and 30 are/stand rejected under 35 U.S.C. § 112, first paragraph for the reasons of record which are restated below.

The specification, while being enabling for a composition and a method for inhibiting the activity of HIV, does not reasonably provide enablement for a composition and a method for inhibiting antiviral activity in vivo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)).

Nature of the invention. The claims are drawn to a composition comprising a formula of claim 1 wherein the complex possesses antiviral activity in vivo.

State of the prior art. At the time the invention was made, C34 peptides (a 34-residue peptide corresponding to the C-terminal heptad repeat of gp41 of HIV-1 Env; WMEWDREINNYTSLIHSLIEESQNQQEKNEQELL) had been shown to inhibit fusion between HIV-1 and cells. SIV and HIV-2 C34 peptides derived from their respective C-terminal heptad repeats of gp41 had also been shown to inhibit SIV and HIV-2 envelope-mediated fusion. In addition, synthetic C34 peptides from SIV (WQEWERKVDFLEENITALLEEAQIQQEKNMYELQ) had been shown to inhibit HIV-1 infections (see Malashkevich et al.).

Breadth of the claims. The claims are very broad, encompassing a complex that possesses antiviral activity in vivo.

Working examples. One working example is provided in the specification showing the activity of the complex of claim 1 against HIV. No working examples are disclosed in the specification showing the effectiveness of the complex of claim 1 for inhibiting any other viral activity in vivo.

Guidance in the specification. The specification provides little guidance regarding practice of the claimed complex. The specification refers to the use of C34 peptides to inactivate gp41, and thus, prevent or reduce HIV-1 entry into cells (See background) and refers to the synthesis of the modified or conjugated C34 peptides. In addition, there is one example showing the effect of the claimed compounds on HIV-1 activity. The specification does not disclose the effect, if any, the claimed complex has on any other virus.

Predictability of the art. In the instant application, Applicants have not disclosed or shown the effectiveness of the claimed C34 derivatives against viruses other than HIV, citing only that "the viruses that may be inhibited by the peptides include, but are not limited to, all strains of viruses listed, e.g., in US 6,013,263 and US 6,017,536 at Tables V-VII and IX-XIV therein." This extensive list of viruses contains many classes of virus that are completely unrelated to HIV in structure, morphology and mode of infection.

The C34 derivatives of the art are derived from gp41 of HIV-1, HIV-2 or SIV. gp41 has a specific sequence and structure, and the C34 peptides derived from gp41 fold into a specific structure (a coiled coil structure) that interacts with another coiled coil structure of gp41 (see Figures 1 and 4 of Malashkevich et al.). Based on the teachings of the prior art and the structure of C34, it does not appear that the C34 peptides derived from HIV will interact with viruses other than HIV.

Amount of experimentation. It is not known whether the claimed complex have any effect against viruses other than HIV. Applicants have identified compounds, which might be effective against some viruses (e.g., HIV-1 and HIV-2), but essentially all of the work required

to ultimately develop a composition and treatment method for viruses other than HIV has been left for others.

Given the breadth of the claims, the lack of guidance in the specification, and the predictability of the art, it would require undue experimentation for one skilled in the art to use the claimed composition and method.

Applicant's arguments were carefully considered but were not found persuasive. Applicant contends that in order to meet the enablement requirement an application need describe no more than one method of making and using the composition. However, the examiner contends that the scope of the instantly claimed composition is broader than what is disclosed in the instant claims. Applicants have identified compounds, which might be effective against some viruses (e.g., HIV-1 and HIV-2), but essentially all of the work required to ultimately develop a composition and treatment method for viruses other than HIV has been left for others. Applicants have not disclosed or shown the effectiveness of the claimed C34 derivatives against viruses other than HIV, citing only that "the viruses that may be inhibited by the peptides include, but are not limited to, all strains of viruses listed, e.g., in US 6,013,263 and US 6,017,536 at Tables V-VII and IX-XIV therein." This extensive list of viruses contains many classes of virus that are completely unrelated to HIV in structure, morphology and mode of infection.

New Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites SEQ ID NO's containing Y1, Y2, Y3, etc., but fails to identify if the Y1, Y2, Y3, etc. are the amino acid tyrosine or other embodiments of amino acids. Therefore, the metes and bounds of the claim are unclear. Appropriate correction is requested.

Conclusion

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROY TELLER whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
4/21/10

/Christopher R. Tate/
Primary Examiner, Art Unit 1655